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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,864	08/25/2000	Howard M Johnson	UF-243X	6790

23557 7590 01/28/2002

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EXAMINER	
ANDRES, JANET L	
ART UNIT	PAPER NUMBER
1646	15

DATE MAILED: 01/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/648,864	JOHNSON ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 9 and species election of interferon tau chimeras is acknowledged. Applicant has cancelled claims 1-24 and added new claims 25-39, drawn to the elected invention. The restriction requirement is made final.

Priority

2. Applicant's priority claim to 60/151026, filed 27 August 1999, is acknowledged.

Information Disclosure Statement

3. Applicant's information disclosure statements filed in paper nos. 4, 5, and 6 have been considered in full.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using interferons and interferon chimeras, does not reasonably provide enablement for methods using biologically active fragments of these molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant has described methods using interferons to reduce IgE levels, and methods are also known in the prior art (see below). However, applicant has not described methods using

DETAILED ACTION

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1. Applicant's election without traverse of Group I in Paper No. 9 and species election of interferon tau chimeras is acknowledged. Applicant has cancelled claims 1-24 and added new claims 25-29, drawn to the elected invention. The restriction requirement is made final.

Priority

2. Applicant's priority claim to 60/151026, filed 27 August 1999, is acknowledged.

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fragments of these molecules, nor has Applicant set forth the characteristics of such biologically active fragments so that one of skill in the art could predictably identify interferon fragments that could be used as claimed. Applicant has not described the properties or characteristics the interferons that are required for activity. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of fragments potentially meeting the limitations of the claims when the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structures or conserved sequences are necessary for the claimed function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

6. Claims 25-39 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has methods using interferons to decrease IgE levels and methods are also known in the art. However, the claims are drawn to methods using biologically active fragments, and thus encompass methods using molecules that vary substantially in length and also in composition. There is no description of the required structural and functional features of the such fragments, or of the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what fragments would possess the same defining characteristics. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus of methods using fragments of interferons.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to methods using a type I interferon, but include interferon gamma, which is not a type I interferon. Thus one of skill in the art would not be able to determine what molecules were encompassed.

Claim 36 is rejected as indefinite in the recitation of "an IgE-related condition". There is no definition in the specification of an "IgE-related condition". One of skill in the art would not be able to determine what conditions Applicant intended to encompass; IgE is presumable involved in some way in many different conditions.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 25, 26, 34, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Pene et al. (Proc. Natl. Acad. Sci. USA, 1988, vol. 85(18), pages 6880-6884). Pene et al. teaches downregulation of IgE production by interferons alpha and gamma, thus anticipating claims 25 and 26. Pene et al. further teaches that this downregulation occurs through effects on B cells, anticipating the limitations of claim 34. The experiments performed by Pene et al. were *in vitro*,

as claimed in instant claim 38 and the interferons were administered in PBS, a pharmacologically acceptable carrier as claimed in claim 39.

11. Claims 25, 26, 33-37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gruschwitz et al. (Int. Arch. Allergy Immunol. 1993, vol. 101, pages 20-30). Grushwitz et al. teaches use of interferon alpha-2b to treat atopic eczema and further teaches that this method results in downregulation of IgE.

12. Claims 25, 26, and 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kimata et al. (Allergy, 1995, vol. 50, pages 837-840). Kimata et al. teaches use of interferon alpha to treat atopic dermatitis and similarly teaches decreases in IgE. Kimata et al. further reports *in vitro* inhibition of IgE production (p. 839), anticipating the limitations of claim 38.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pene et al., Gruschwitz et al., or Kimata et al. as applied to claims 26 and 26 above, and further in view of WO 97/39127 (Johnson et al., 1997). Pene et al., Grushwitz et al., and Kimata et al. teach as set forth above but fail to teach interferon tau or interferon tau/ interferon alpha chimeras. WO 97/39127 teaches that interferon tau binds to the same receptor as type I interferons (p. 5) and that it has effects similar to those of interferon alpha, including anti-viral activity (pages 21-24) and anti-proliferative activity (pages 24-26). WO 97/39127 also teaches that interferon tau activates the signaling molecules activated by interferon alpha. WO 97/39127 further teaches the hybrid fusion proteins between interferon tau and interferon alpha of instant claims 28-32 and specifically teaches chimeras incorporating amino acids 1-28 of interferon tau and 29-167 of an interferon alpha (p. 7), which is "about 1 to about 27" and "about 28 to about 166" as claimed in instant claim 31. WO 97/39127 further teaches the use of these fusion proteins to treat disease, including allergy (p. 26). WO 97/39127 fails to teach use of interferon tau or interferon chimeras to decrease IgE levels. However, it would have been obvious to one of ordinary skill in the art to combine the teachings of Pene et al., Grushwitz et al., or Kimata et al. with those of WO 97/39127 to use interferon tau or hybrids thereof to decrease IgE production. One of ordinary skill would have been motivated to do so because WO 97/39127 teaches that these proteins act through the same receptor as interferon alpha and have similar effects. Thus one of ordinary skill would have expected that the proteins could be used in the same way. Further, since Pene et al., Gruschwitz et al, and Kimata et al. teach that interferon gamma, which is not a type I interferon, has similar effects, one of ordinary skill would further have expected the desired suppression to be a general property of interferons. One of ordinary skill would further have

been motivated to combine these teachings because WO 97/39127 teaches that interferon tau and chimeras thereof are less toxic than interferon alpha.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
January 25, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600